

## **REMARKS**

Claims 18-36 are pending in this application. In this Amendment, independent claims 18, 34, and 35 have been amended.

Support for the amendments to the claims can be found, for example, in paragraph [0021] of the specification. No new matter has been added.

### ***Provisional Obviousness-Type Double Patenting Rejections***

Claims 18-24, 26, 27, 29-31, and 33-36 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 16-32 of copending Application No. 10/882,580.

Claims 25, 28, and 32 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 16-32 of copending Application No. 10/882,580, further in view of Mansouri (U.S. Patent App. No. 2001/0006680).

Applicants respectfully traverse these rejections.

Because these are provisional obviousness-type double patenting rejections, Applicants request that these rejections be held in abeyance until there is an indication of allowable subject matter in one of these two pending applications.

### ***Rejections under 35 U.S.C. § 103(a)***

Claims 18-24, 26-27, 29-31, and 36 also were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Soerens et al. (U.S. Patent No. 6,967,261) in view of Chou '893 (U.S. Publ. No. 2003/0204893) and/or Hahn et al. (U.S. Publ. No. 2003/0124202) and/or Murray et al. (U.S. Patent No. 4,920,158). Claims 25, 28, and 32 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Soerens et al. in view of Chou '893 and/or Hahn et al. and/or Murray et al., and further in view of Mansouri (U.S. Publ. No. 2001/0006680).

Claims 18-24, 26-27, 29, 31, and 33-35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chou '893 in view of Hahn et al. and/or Murray et al., and further in view of Applicants' admissions. Claims 25, 28, and 32 were also

rejected under 35 U.S.C. 103(a) as being unpatentable over Chou '893 in view of Hahn et al. and/or Murray et al. as applied above, and further in view of Mansouri.

Claims 18-29 and 31-35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chou '582 (U.S. Patent No. 6,953,582) in view of Mansouri and Chou '893 and/or Hahn et al. and/or Murray et al., and further in view of Applicants' admissions. Claims 30 and 36 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chou '582 in view of Mansouri and Chou '893 and/or Hahn et al. and/or Murray et al., and further in view of Soerens et al.

Applicants respectfully traverse all rejections.

### ***The Presently-Claimed Invention***

The presently-claimed invention relates, generally, to an elastomeric article including an elastomeric layer having a skin-contacting elastomeric surface and a coating composition provided directly on the skin-contacting elastomeric surface of said elastomeric layer. The coating composition is in a dry state and includes at least one polyhydric alcohol moisturizer and at least one alphahydroxy lactone. The composition is water-soluble and hydratable upon contact with skin.

In addition, the presently-claimed invention also relates to an examination glove including an elastomeric layer having a skin-contacting elastomeric surface and a coating composition provided directly on the skin-contacting elastomeric surface of said elastomeric layer. The coating composition is in a dry state and includes at least one polyhydric alcohol moisturizer and at least one alphahydroxy lactone. The composition is water-soluble and hydratable upon contact with skin.

The presently-claimed invention further relates to a surgeon's glove including an elastomeric layer having a skin-contacting elastomeric surface and a coating composition provided directly on the skin-contacting elastomeric surface of said elastomeric layer. The coating composition is in a dry state and includes at least one polyhydric alcohol moisturizer and at least one alphahydroxy lactone. The composition is water-soluble and hydratable upon contact with skin.

The claimed elastomeric articles are particularly effective for moisturizing the skin that is in contact with the article, even after the article has been removed. The articles

of the presently-claimed invention provide beneficial therapeutic treatments include improved skin moisturization, reduced flaking, softness of feel, improved skin elasticity and firmness, reduced redness and irritation, and reduced appearance of wrinkles.

***Rejections based on Soerens et al., Chou '893,  
Hahn et al., Murray et al., and Mansouri***

Claims 18-24, 26-27, 29-31, and 36 also were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Soerens et al. in view of Chou '893 and/or Hahn et al. and/or Murray et al. Claims 25, 28, and 32 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Soerens et al. in view of Chou '893 and/or Hahn et al. and/or Murray et al., and further in view of Mansouri.

Soerens et al. is cited for disclosing an elastomeric article comprising an elastomeric layer having a skin-contacting surface, and a coating composition on the skin-contacting surface of the elastomeric layer. The coating composition is in a dry state, and includes at least one polyhydric alcohol moisturizer (i.e., glycerin). The coating composition may include chitosan as an antimicrobial agent. However, the Office Action recognizes that Soerens et al. fails to disclose that the coating composition includes at least one alphahydroxy lactone.

Hahn et al. is cited for disclosing that gluconolactone is an exfoliant. Murray et al. is cited for disclosing the addition of gluconolactone to wound dressings or therapeutic skin coating materials for use as a drying aid, plasticizer, and/or for aesthetic purposes.

Chou '893 is cited for disclosing adding hydroxyacids similar to those disclosed by Hahn et al. for use in a therapeutic coating composition.

Mansouri is cited for disclosing the addition of pantothenol to skin care lotions that are compatible with latex glove use, where the lotions provide "vitamin enhancement" to skin.

The Office Action takes the position that it would have been obvious to modify Soerens et al. to include an exfoliant such as gluconolactone in view of the coating compositions of Chou '893, Hahn et al., and/or Murray et al.; to include pantothenol in

view of the coating compositions of Mansouri; and to include chitosan in view of the coating compositions of Soerens et al.

Applicants submit that Chou '893 does not qualify as prior art under 35 U.S.C. § 102(e), because the subject matter of independent claims 18, 34, and 35 was invented in the U.S. prior to the May 2, 2002 effective date of Chou '893. Applicants submit herewith a Declaration under 37 CFR § 1.131 of inventors Shiping Wang, Yun-Siung Tony Yeh, and Wei Cheong Wong, who conceived the subject matter of at least independent claims 18, 34, and 35.<sup>1</sup> Exhibits A, B, and C demonstrate that the subject matter of claims 18, 34, and 35 was conceived prior to the U.S. filing date of Chou '893, specifically before May 2, 2002. This evidence of activity in the U.S. properly establishes a date of invention under 35 U.S.C. § 104(a)(1).

Further, even when combined, and Applicants do not concede that the combination of Soerens et al., Hahn et al., Murray et al., and Mansouri is proper, the cited references still fail to disclose or suggest the elastomeric articles of the presently-claimed invention, in which the coating composition is provided directly onto the skin-contacting elastomeric surface of the elastomeric article.

The bandages disclosed in Soerens et al. have a glycerin coating provided on an absorbent poly(ethyleneoxide)-based compound that is located between the elastomeric base layer of the bandage and the skin to which the bandage is applied. The glycerin coating of Soerens et al. is not a dry coating composition provided directly on a skin-contacting elastomeric surface. Applying moisturizing agents onto the elastomeric portion of the bandage would adversely affect the ability of the bandage to adhere to the skin, thereby rendering it ineffective for its intended use.

None of Hahn et al., Murray et al., and/or Mansouri describe an elastomeric article including an elastomeric layer having a skin-contacting elastomeric surface, and a coating composition provided directly on the skin-contacting elastomeric surface of the elastomeric layer. Their further combination with Soerens et al. fails to remedy its deficiencies.

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<sup>1</sup> Co-inventor James Owens contributed to the subject matter of at least one dependent claim.

Applicants therefore submit that claims 18-36 are patentable over any combination of Soerens et al., Hahn et al., Murray et al., and Mansouri, and respectfully request withdrawal of these rejections.

***Rejections based on Chou '893, Hahn et al. and/or Murray et al.***

Claims 18-24, 26-27, 29, 31, and 33-35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chou '893 in view of Hahn et al. and/or Murray et al., and further in view of Applicants' "admission." Claims 25, 28, and 32 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Chou '893 in view of Hahn et al. and/or Murray et al. as applied above, and further in view of Mansouri.

Chou '893 is cited for disclosing an elastomeric article comprising an elastomeric layer having an outer surface and a skin-contacting surface, and a coating composition on the skin-contacting surface of the elastomeric layer. The coating composition is in a dry state, and includes at least one polyhydric alcohol moisturizer (i.e., glycerin). The coating composition is water-soluble and hydratable upon contact with skin. Chou '893 discloses adding hydroxyacids to a coating composition. However, the Office Action recognizes that Chou '893 fails to disclose that the coating composition includes at least one alphahydroxy lactone.

Hahn et al. is cited for disclosing that gluconolactone is an exfoliant, and the Office Action takes the position that they are substantially identical to those disclosed by Chou '893. Murray et al. is cited for disclosing the addition of gluconolactone to wound dressings or therapeutic skin coating materials for use as a drying aid, plasticizer, and/or for aesthetic purposes.

Applicants' "admission" is that citric acid is a known hydration promoter.

Mansouri is cited for disclosing the addition of pantothenol to skin care lotions in order to provide "vitamin enhancement" to skin.

The Office Action takes the position that it would have been obvious to modify the device of Chou '893 to include an exfoliant such as gluconolactone in view of the coating compositions of Hahn et al. and/or Murray et al., and to include pantothenol in view of the coating compositions of Mansouri.

As set forth above, Chou '893 does not qualify as prior art under 35 U.S.C. § 102(e), because the subject matter of at least independent claims 18, 34, and 35 was invented in the U.S. prior to the May 2, 2002 effective date of Chou '893. For at least the reasons set forth above, Applicants submit that even in combination, Hahn et al., Murray et al., and Mansouri fail to disclose or suggest the elastomeric articles of the presently-claimed invention, in which the coating composition is provided directly on the skin-contacting elastomeric surface of the elastomeric article.

Applicants therefore submit that claims 18-36 are patentable over any combination of Hahn et al., Murray et al., and Mansouri, and respectfully request withdrawal of these rejections.

***Rejection based on Chou '582, Mansouri, Chou '893, Hahn et al., Murray et al., and Soerens et al.***

Claims 18-29 and 31-35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chou '582 in view of Mansouri and Chou '893 and/or Hahn et al. and/or Murray et al., and further in view of Applicants' "admission." Claims 30 and 36 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chou '582 in view of Mansouri and Chou '893 and/or Hahn et al. and/or Murray et al., and further in view of Soerens et al.

Chou '582 is cited for disclosing an elastomeric article comprising an elastomeric layer having a skin-contacting surface, and a coating composition on the skin-contacting surface of the elastomeric layer. The coating composition is in a dry state, and is water soluble and hydratable upon skin contact. The coating composition comprises aloe vera, and "alternatively or additionally ... any other skin-soothing or skin-moisturizing substance or mixture that can be dried onto the inside of a glove and that, in the dry form, is mixed with moisture that consists only of perspiration from a hand during wearing of the glove and moisturizes the hand." (See col. 8, lines 24-34.) However, the Office Action recognizes that Chou '582 fails to disclose that the coating composition includes at least one polyhydric alcohol and at least one alphahydroxy lactone.

Mansouri is cited for disclosing the addition of a polyhydric alcohol to a coating composition as an antimicrobial agent or a humectant (i.e., sorbitol and/or glycerin).

Hahn et al. is cited for disclosing that gluconolactone is an exfoliant. Murray et al. is cited for disclosing the addition of gluconolactone to wound dressings or therapeutic skin coating materials for use as a drying aid, plasticizer, and/or for aesthetic purposes.

Chou '893 is cited for disclosing adding hydroxyacids similar to those disclosed by Hahn et al. for use in a therapeutic coating composition.

Applicants' "admission" is that citric acid is a known hydration promoter.

Soerens et al. is cited for disclosing that the coating composition may include chitosan as an antimicrobial agent.

The Office Action takes the position that it would have been obvious to modify Chou '582 to include gluconolactone as an exfoliant, drying aid, plasticizer, or for aesthetic purposes in view of the coating compositions of Mansouri, Chou '893, Hahn et al., and/or Murray et al.; to include citric acid and pantothenol in view of the coating compositions of Mansouri; and to include chitosan in view of the elastomeric articles of Soerens et al.

As set forth above, Chou '893 does not qualify as prior art under 35 U.S.C. § 102(e), because the subject matter of at least independent claims 18, 34, and 35 was invented in the U.S. prior to the May 2, 2002 effective date of Chou '893.

Chou '582 discloses elastomeric gloves having a coating formed from an aloe vera solution that is dried on their inner surfaces. The coating is said to condition and soothe the hands, and prevent growth of microorganisms. Although Chou '582 generically discloses that other ingredients may be included in the coating, no disclosure regarding how to incorporate any other ingredients into the coating is provided.

Mansouri discloses skin care moisturizers and cleansers that may include absorption enhancers (hydroxyapatite), antimicrobial function enhancers, bound lipid removers, humectants, emollients, and extracts of botanical herbs. They are designed to be compatible with latex glove use. Mansouri discloses a composition that includes at least one polyhydric alcohol moisturizer, but fails to disclose or suggest at least one alphahydroxy lactone, or that the composition is applied directly to a skin-contacting elastomeric surface of an elastomeric article.

Hahn et al. discloses topical compositions that include water-soluble divalent strontium cations for inhibiting skin irritation caused by chemical and/or environmental irritants. Hahn et al. discloses that “some chemicals indirectly cause skin to become more sensitive to other chemicals or environmental conditions which would not normally cause irritation.” See paragraph [0007]. Hahn et al. continues:

Many chemicals which act as skin “exfoliants” such as ... gluconolactone ... may cause skin to become more sensitive to irritation triggered by other topically-applied chemicals such as moisturizers.

Hahn et al. only discloses using irritants such as gluconolactone in compositions that include a sufficient amount of strontium cations to reduce its irritation potential. Thus, Hahn et al. teaches away from a composition including at least one polyhydric alcohol moisturizer and at least one alphahydroxy lactone, as such a composition may lead to skin irritation.

Murray et al. discloses hydrogel-forming wound dressing materials that provide effective transmission of moisture from the wound to the environment. The hydrogel-forming material is made of first and second hydrophilic polymers, and may include a plasticizer, which may be gluconolactone. The hydrogels of Murray et al. are water resistant, and form films over a wound that provide a barrier to microorganisms. Murray et al. describes testing the hydrogels by applying them to a hand and then covering the hand with an elastomeric glove until beads of water form within the glove for the “Occlusive Glove Test” (see column 12 and Examples 2 and 25). Applicants submit that one skilled in the art would not look to the water-resistant hydrogel of Murray et al. in order to arrive at the presently-claimed coated gloves having a dry coating composition that is water soluble.

The bandages disclosed in Soerens et al. have a glycerin coating provided on an absorbent poly(ethyleneoxide)-based compound that is located between the elastomeric base layer of the bandage and the skin to which the bandage is applied. The glycerin coating of Soerens et al. is not a dry coating composition provided directly on a skin-contacting elastomeric surface. Applying moisturizing agents onto the elastomeric



portion of the bandage would adversely affect the ability of the bandage to adhere to the skin, thereby rendering it ineffective for its intended use.

Accordingly, even when combined, and Applicants do not concede that the combination of Chou '582, Mansouri, Hahn et al., Murray et al., and Soerens et al. is proper, the cited references still fail to disclose or suggest the elastomeric articles of the presently-claimed invention, in which the elastomeric article includes an elastomeric layer having a skin-contacting elastomeric surface, and a coating composition provided directly on the skin-contacting surface of the elastomeric layer, where the coating composition is in a dry state and includes including at least one polyhydric alcohol moisturizer and at least one alphahydroxy lactone.

Applicants therefore submit that claims 18-36 are patentable over any combination of Chou '582, Mansouri, Hahn et al., Murray et al., and Soerens et al., and respectfully request withdrawal of these rejections.

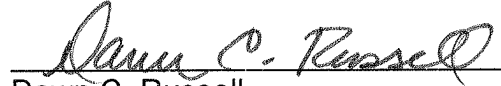
### **CONCLUSION**

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 18-36, and the prompt issuance of a Notice of Allowance are respectfully requested.

Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing docket number **029714.00054**.

Respectfully submitted,

A handwritten signature in cursive script, reading "Dawn C. Russell", written over a horizontal line.

Dawn C. Russell  
Registration No. 44,751  
Attorney for Applicant

Attachment: Declaration under 37 C.F.R. § 1.131

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